REMARKS/ARGUMENTS

The Invention

The invention pertains to a composition comprising an interluekin-2 receptor associated polypeptide, wherein the polypeptide is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, and methods of purifying the same.

The Pending Claims

Claims 1, 3, 5, 9, 11-15, and 22-29 are pending of which, claim 26-29 are new. Claims 1, 3, 5, and 22-29 are directed to compositions comprising interleukin-2 receptor associated polypeptides, which are capable of forming a complex with monoclonal antibodies produced by the hybridoma PTA-82. Claims 9 and 11-15 are directed to methods of purifying the subject interleukin-2 receptor associated polypeptides.

The Amendments to the Claims

The limitation recited in dependent claim 4 has been added to independent claims 1, 3, 24, and 25, and claim 4 has been canceled. Amended claims 1, 3, 24, and 25 and new claims 26-29 recite that the claimed interleukin-2 receptor associated polypeptides is expressed from cells selected from the group consisting of Kit-225 cells and HuT 102 cells. These amendments are supported by the specification at, for example, page 31, line 23, through page 32, line 22, and by original claim 4. Claim 9 has been amended to recite method steps (d) and (e) for purifying the claimed interleukin-2 receptor associated polypeptides Method step (d) recites eluting the claimed interleukin-2 receptor associated polypeptide from the antibody complex of method step (c), and method step (e) recites the isolation of said polypeptide. The amendments to claim 9 are supported by the specification at, for example, page 35, line 23, through page 36, line 25. Accordingly, no new matter has been added by way of these amendments.

The Office Action

Claims 1, 3-5, 9, 11-15, and 22-25 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Claims 1, 3-5, 9, 13-15, and 22-25 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Colamonici et al. (*J. Immunol.*, *145*, 155-160 (1990)). The claims have been amended to place the application in condition for allowance. Accordingly, reconsideration of these rejections is respectfully requested.

Discussion of the Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action contends that the metes and bounds of claims 1, 3, 24 and 25 cannot be determined because the structures of the polypeptides in the claimed composition are unclear. The Office Action goes on to state that the addition of a limitation reciting the source of the polypeptide would overcome this rejection. During a telephone interview with Examiner Jiang on January 12, 2006, Examiner Jiang confirmed that adding a limitation directed to the cell lines from which the claimed polypeptides are derived would overcome the rejection of claims 1, 3, 5, and 22-25 under Section 112, second paragraph. During the interview Examiner Jiang also stated that adding method steps to claim 9 reciting elution or some means by which the claimed polypeptides are disassociated from the polypeptide antibody complex, and finally, isolation of the claimed polypeptides would overcome the rejection of claims 9, and 11-15 under Section 112, second paragraph. Applicants wish to thank Examiner Jiang for the courtesy extended during the interview. In an effort to advance prosecution of this application, and not in acquiescence of the rejection, Applicants have amended the claims as suggested by Examiner Jiang. In view of the foregoing, Applicants submit that claims 1, 3, 5, 9, 11-15, and 22-25 particularly point out and distinctly claim the present invention. Accordingly, Applicants respectfully request the Office to withdraw its rejection of claims 1, 3-5, 9, 11-15, and 22- 25 under Section 112, second paragraph.

Discussion of Rejection Under 35 U.S.C. §§ 102(b)/103(a)

Claims 1, 3-5, 9, 13-15, and 22-25 are rejected under Section 102(b) as allegedly anticipated by, or in the alternative, under Section 103(a) as allegedly obvious in view of, Colamonici et al. This rejection is traversed for the reasons set forth below.

Applicants resubmit that the Section 102(b)/103(a) rejection is improper (M.P.E.P. § 706.02(m)) given that the claims are ascertainable, and thus, should be withdrawn.

Despite the improper rejection, the Office Action alleges that Colamonici et al. discloses polypeptides having molecular weights of *about* 32-34 kDa (i.e., 37 kDa), and *about* 26 kDa-28 kDa (i.e., 20 kDa), which associate with a subunit of the IL-2 receptor.

Colamonici et al. specifically discloses IL-2 receptor associated polypeptides of 37 kDa and 20 kDa, which were immunoprecipitated from HUT-102 and MT-1 cells with anti-Tac and 7G7/B6 monoclonal antibodies (see Colamonici et al. at page 159, second column). Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 executed by Thomas A. Waldmann, M.D., which declares that the 32-34 kDa and 26-28 kDa polypeptides of the pending claims are different polypeptides than the 37 kDa and 20 kDa polypeptides disclosed in Colamonici et al. The Waldmann Declaration includes side-by-side comparative data from SDS-PAGE experiments which distinguish the claimed polypeptides from those polypeptides recited in Colamonici et al. In the experiment, both sets of polypeptides

(claimed polypeptides vs. polypeptides disclosed in Colamonici et al.) were simultaneously immunoprecipitated from solubilized MT-1 cells using 5F7 monoclonal antibody and anti-Tac antibody, respectively. The immunoprecipitated polypeptides were collected and electrophoresed through an SDS polyacrylamide gel. Analysis of the gel revealed that the claimed polypeptides correspond to unique molecular weight gel-bands relative to the polypeptides immunoprecipitated with anti-Tac antibody, therefore, emphasizing the distinction between the claimed polypeptide and those disclosed in Colamonici et al. Such results eliminate any potential discrepancies in gel dependent molecular weight assessments caused by variations between individual gels.

Furthermore, the Waldmann Declaration provides data from an SDS-PAGE analysis, wherein cell lysate from Kit 225 cells was immunoprecipitated using 5F7 monoclonal antibody, and the resulting immunoprecipitate was electrophoresed against two independent sets of molecular weight markers. A gel analysis of the immunoprecipitate revealed two major polypeptide bands. The molecular weights associated with each band, relative to the molecular weight markers, further provides evidence that the claimed polypeptides differ from those polypeptides disclosed in Colamonici et al.

Additionally, a pre-clearance experiment is described in the Waldmann Declaration, which provides data from an SDS-PAGE analysis demonstrating the presence of the claimed polypeptides in cell lysate from Kit 225 cells after the lysate had been pre-cleared multiple times with anti-Tac antibody. Specifically, the anti-Tac, pre-cleared lysate was further immunoprecipitated with anti-5F7 antibody. The resulting immunoprecipitate was then subjected to SDS-PAGE analysis. Evaluation of the gel containing the resultant anti-5F7 immunoprecipitate revealed the presence of the claimed polypeptides at the same intensity and gel location relative to polypeptides immunoprecipitated from Kit 225 cell lysate using anti-5F7 antibody, wherein the cell lysate was not previously pre-cleared with anti-Tac. The experimental results further point out that anti-Tac antibody does not recognize the claimed polypeptides, contradicting the Office's contention that said polypeptides are disclosed in Colamonici et al.

Finally, the Waldmann Declaration discloses the results of an experiment, which demonstrates the presence of an about 32-34 kDa IL-2 receptor associated polypeptide on the surface of Kit 225 cells and the lack of expression of the same polypeptide on MLA-144 cells, as demonstrated by flow cytometry. The experimental results support also show that the 37 kDa protein disclosed in Colamonici et al. is a different polypeptide than the claimed about 32-34 kDa polypeptide. Colamonici et al. indicates that MLA-144 cells are positive for expression of the 37 kDa polypeptide disclosed therein, and the experiments recited in the Declaration demonstrate that MLA-144 cells are negative for expression of the claimed 32-34 kDa polypeptide, yielding the conclusion that the polypeptides are different.

Colamonici et al. also does not render obvious the subject matter of the pending claims. As discussed above, Colamonici et al. does not disclose or suggest an IL-2 receptor associated protein that is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, and Colamonici et al. does not disclose a polypeptide having the above recited characteristics and a molecular weight of about 32-34 kDa or about 26-28 kDa. Colamonici et al. does not suggest to one of ordinary skill in the art a polypeptide having the claimed characteristics including a molecular weight of about 32-34 kDa or about 26-28 kDa, nor would the teachings of Colamonici et al. motivate one skilled in the art to isolate such polypeptides. On the contrary, in view of the teachings of Colamonici et al. one skilled in the art would be left, not with the claimed polypeptides, but with materially different polypeptides, as demonstrated by the Waldmann declaration. Thus, in view of the deficiencies Colamonici et al., one of ordinary skill in the art could not rely on the teachings or suggestions of Colamonici et al. to arrive at the claimed invention.

For the foregoing reasons, the Office Action fails to establish the criteria for a proper anticipation rejection, or a *prima facie* case of obviousness, and the Section 102/103 rejection should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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